

### REMARKS

This responds to the Office Action dated May 19, 2004. Claims 73, 131, 132, 134, 138, 141, 143 and 147 of this application are independent and each of the remaining pending claims depends from one of the independent claims.

The Examiner rejected each of the independent claims 73, 131, 132, 134, 138, 141, 143 and 147 under 35 U.S.C. 103(a) as being unpatentable in part based on the publication of "drkoop.com & Quintiles Launch Service to Recruit Clinical Trial Patients on the Internet," PR Newswire, June 28, 1999 (the "drkoop.com press release"). The individual rejections are discussed further below. Generally, unless it is a statutory bar, a rejection based on a publication may be overcome by proving that the invention of the claimed subject matter by applicant occurred prior to the date of the cited publication. See M.P.E.P. 715.01. In instances, such as here, where applicant invented the claimed subject matter prior to the date of the cited publication, the rejection may be overcome by filing a specific affidavit or declaration under 37 C.F.R. 1.131 establishing the date of invention for the subject claims as prior to the date of the cited publication. M.P.E.P. 715.01(d). A declaration is permitted instead of an affidavit. 37 C.F.R. 1.68.

Accordingly, applicant respectfully directs the Examiner's attention to the following declarations: the Declaration of James D. Marks, applicant of the claimed subject matter (Exhibit 1, hereinafter "the J. Marks Dec."); the Declaration of Bonnie Goldman (Exhibit 2; hereinafter "the B. Goldman Dec."); the Declaration of Dahlia Elsayed (Exhibit 3, hereinafter "the D. Elsayed Dec."); and, the Declaration of Jason K. Dewey (Exhibit 4, hereinafter "the J. Dewey Dec."). Also attached as Exhibit 5 are Exhibits A, B, C and D which contain evidence relevant to each of the declarations in Exhibits 1, 2, 3 and 4. The Declarations establish that applicant completed the invention as described and claimed in the subject patent application, including each element of each independent claim. In addition, the completion of the invention for each independent claims occurred in the United States prior to the publication of the June 28, 1999 drkoop.com press release. More particularly, the Declarations establish the teachings of each element of each independent claim based on work completed prior to June 28, 1999,

as set forth in detail below:

### INDEPENDENT CLAIM 73

(Claim 73, a) "A method of on-line recruitment of candidates," is established by the J. Marks Dec. "[t]he Health Survey Questionnaire was first installed on a server for posting on [www.thebody.com](http://www.thebody.com) and made accessible to members of the public through access to [www.thebody.com](http://www.thebody.com) via the Internet between May 21, 1999 and, at the latest, May 24, 1999, the first date for which [www.thebody.com](http://www.thebody.com) received responses to the Questionnaire (see Exhibit C)." (Para. 4; see also the B. Goldman Dec., para. 4.) Also, see Exhibit D, "[t]he Body... [http://www.thebody.com/surveys/health\\_survey.html](http://www.thebody.com/surveys/health_survey.html)... is compiling a database of volunteers' health information for possible participation in upcoming medical trials" (attested to in the J. Marks Dec., para. 7 and the B. Goldman Dec., para. 7).

(Claim 73, b) "[F]or a plurality of clinical trials..." is established by the J. Marks Dec. "[t]he purpose of the Health Survey Questionnaire was to solicit health and contact information from members of the public, provided with gratuitous access to the web site, for possible participation in one or more upcoming clinical trials." (Para. 4; see also the B. Goldman Dec., para. 4.)

(Claim 73, c) "[R]eceiving over a network from a computer terminal... an individual's on-line electronic consent to an agreement volunteering for consideration as a potential candidate for the clinical trials..." is established by the J. Marks Dec. "[i]n order to submit the data which appears in the responses of Exhibit C to [www.thebody.com](http://www.thebody.com), each respondent had to provide electronic consent to a Participation Agreement. The Participation Agreement required that the respondent consent to volunteer for consideration as a potential candidate for existing and future clinical trials. Failure to provide electronic consent to the Participation Agreement precluded submission of the response so that no response would be generated. As a result, each response in Exhibit C corresponds to a respondent who provided electronic consent to volunteer for

consideration as a potential candidate for existing and future clinical trials." (Para. 6.c.iii.; see also the B. Goldman Dec., para. 6.c.iii.) Exhibit C is a true copy of the responses received from the on-line Health Survey Questionnaire. (Attested to in the J. Marks Dec., para. 6.c., B. Goldman Dec., para. 6.c., D. Elsayed Dec., para. 3.)

(Claim 73, d) "[R]eceiving over the network... at least one of the individual's medical information and personally identifying information;" is established by Exhibit C and the J. Marks Dec. para. 6.c.iii, the B. Goldman Dec., para 6.c.iii, the D. Elsayed Dec., para. 5.c. and the J. Dewey Dec. , para. 3. The medical and personally identifying information from Exhibit C was redacted to protect the privacy of the respondents and the confidentiality of the data. The content of the redacted data as being medical and personally identifying information is attested to in the J. Marks Dec., para. 6.c.iii, the B. Goldman Dec., para 6.c.iii, the D. Elsayed Dec., para. 5.c. and the J. Dewey Dec. , para. 3 who redacted the information.

(Claim 73, e) "[A]dding the at least one of the individual's medical information and personally identifying information to a database..." is established by the J. Marks Dec. and the D Elsayed Dec. The J. Marks Dec. provides "[i] further conceived of, supervised and controlled the design and implementation of a secure database in which the data entered in response to the Health Survey Questionnaire was stored. The first responses to the Questionnaire were received on May 24, 1999." (Para. 5; see also the B. Goldman Dec., para. 5.) The D. Elsayed Dec. establishes that the database was accessed and stored at the offices of Body Health Resources Corp. (hereinafter, "BHRC") prior to June 28, 1999 as follows: "[a]ttached as Exhibit A is a true copy of the jacket cover from the zip disk containing the Health Survey Responses for responses which were received from May 24, 1999 to April 12, 2000. The jacket cover contains the hand written description of the contents as "Health Survey Responses... launched 5/25/99. I provided this hand written note at the time that the data was first stored on the zip disk on or about May 25, 1999." (Para. 5.a.) See also Exhibit B, which is a true copy of the file index listing of the zip disk of Exhibit A, including in column 1 the file name which corresponds

to the date the Health Survey Responses data was saved to the disk. Exhibit B provides that the first storage date was May 27, 1999. However, the responses could have been printed out, thereby establishing the database earlier, i.e., on May 24, 1999 or May 25, 1999. Exhibit B is attested to in the J. Marks Dec. para. 6.b., the B. Golmand Dec., para. 6.b. and the D. Elsayed Dec., para. 5.b. See also Exhibit A, attested to in the J. Marks Dec., para. 6a, the B. Goldman Dec., para. 6a and the D. Elsayed Dec., para. 5.a. Furthermore, this element is established by Exhibit D, attested to in the J. Marks Dec., para. 7 and the B. Goldman Dec., para. 7. Exhibit D provides that "[t]he Body is compiling a database of volunteers' health information for possible participation in upcoming medical trials."

(Claim 73, f) "[A] database of at least one individual..." is established by the J. Marks Dec. "[t]he earliest responses were submitted on May 24, 1999. There are two May 24, 2004 responses, one is a test response submitted by one of BHRC's employees via the public interface at [www.thebody.com](http://www.thebody.com) and the other is from a member of the public unaffiliated with BHRC. In addition, at least two of the responses from May 25, 2004 are from members of the public unaffiliated with BHRC. Therefore, responses to the Questionnaire by multiple members of the public were received prior to the June 28, 1999 publication date of [drkoop.com](http://drkoop.com) press release." (Para. 6.c.ii, see also the B. Goldman Dec., para. 6.c.ii and the J. Dewey Dec., para. 3.) Therefore, as of May 25, 1999 (or at the latest May 27, 1999 when Exhibit B establishes that the responses were stored on the zip disk), the database contained at least three individuals, or members of the public unaffiliated with BHRC; namely, one individual from May 24th and at least two individuals from May 25th.

(Claim 73, g) "[F]or consideration as a potential candidate for the clinical trials..." See the statement of established facts set forth above for claim 73, c.

#### INDEPENDENT CLAIM 131

See generally the statement of established facts set forth above for claim 73.

(Claim 131 alternative to claim 73, f) "[A] database of at least two individuals..." See the statement of established facts set forth above for claim 73 f; namely, the established fact that as of May 25, 1999, the database contained at least three individuals, or members of the public unaffiliated with BHRC.

#### INDEPENDENT CLAIM 132

See generally the statement of established facts set forth above for claim 73 .

(Claim 132 alternative to claim 73, c) "[P]roviding an enrollment interface generated by a server over a computer network for access by a plurality of remote computer terminals, the enrollment interface including an agreement volunteering for consideration as a potential candidate for the clinical trials, whereby a plurality of remote individuals can provide electronic consent to the agreement via the remote computer terminals; receiving the electronic consent from at least two of the remote individuals on the enrollment interface..." See generally the statement of established facts set forth above for claim 73, c.

#### INDEPENDENT CLAIM 134

See generally the statement of established facts set forth above for claim 73.

#### INDEPENDENT CLAIM 138

See generally the statement of established facts set forth above for claim 73.

(Claim 138, h) "[A] secure server generating an agreement..." See the statement of established facts set forth above for claim 73 a.

#### INDEPENDENT CLAIM 141

See generally the statement of established facts set forth above for claims 73, 132 and 138.

### INDEPENDENT CLAIM 143

See generally the statement of established facts set forth above for claims 73, particularly 73 e.

### INDEPENDENT CLAIM 147

See generally the statement of established facts set forth above for claims 73, particularly 73 e.

(Claim 147, i) "[A] method of selecting a candidate..." including "applying selection criterion...", "identifying a potential candidate record which matches the criterion...", "selecting the individual corresponding to the potential candidate record which matches the criterion for possible participation in the clinical trial..." is established by Exhibit D, attested to in the J. Marks Dec., para. 7 and the B. Goldman Dec., para. 7. Exhibit D provides that "[t]he Body is compiling a database of volunteers' health information for possible participation in upcoming medical trials. Clinical researchers... often contact The Body for information regarding volunteers for participation in various clinical trials..., and The Body is building this database for the purpose of facilitating these requests." Therefore, as of the date of Exhibit D, May 26, 1999, BHRC was establishing the database for use by clinical trials researchers to select potential candidates.

The Examiner rejects independent claims 73, 131, 132, 134, 138, 141 and 143 under 35 U.S.C. 103(a) as being unpatentable in part based on the June 28, 1999 publication of the drkoop.com press release (see the Office Action, page 2, para. 4). The Examiner also rejects independent claim 147 under 35 U.S.C. 103(a) as being unpatentable in part based on the June 28, 1999 publication of the drkoop.com press release (see the Office Action, page 23, para. 9). The remaining rejections are directed to dependent claims. As a result of the facts established in the attached Declarations (Exhibits 1, 2, 3 and 4) and the corresponding Exhibits A, B, C and D (Exhibit 5) as well as the analysis provided above for each of the independent claims, it is clear that applicant James D.

Marks completed the invention claimed in each of the independent claims prior to the June 28, 1999 publication of drkoops.com press release. This completed work is an actual reduction to practice of the claimed invention since it was available to the public and executed by multiple members of the public, including at least three members of the public by May 25, 1999, and the database generated by the implementation of the invention was accessed, printed out and/or stored for at least three members of the public as early as May 25, 1999 or as late as May 27, 1999. Therefore, a showing of diligence is not required. As a result, the June 28, 1999 publication of the drkoop.com press release is not available as a reference against the subject claims. Since each independent claim (and likewise the claims which depend from them) was rejected under 35 U.S.C. 103(a) in part based on June 28, 1999 publication of the drkoop.com press release, at least one element of each independent and each dependent claim is not taught by the June 28, 1999 publication of drkoop.com press release (as well as not being taught by any of the other cited references, see the March 5, 2004 Amendment in the subject prosecution history). Applicant consequently asserts that each of the rejections has been overcome and requests that each of the rejections therefore be withdrawn.

Each and every point raised in the Office Action dated May 19, 2004 has been addressed on the basis of the above remarks. Reconsideration and withdrawal of the rejections are respectfully requested. In addition, applicant submits that the cited reference, the June 28, 1999 drkoop.com press release publication, is no longer a reference for the elements which the Examiner asserts are taught by the publication. Thus, applicant submits that independent claims 73, 131, 132, 134, 138, 141, 143 and 147 are in condition for allowance and respectfully requests that the present application be allowed and passed to issue. Should the Examiner believe that direct contact with the applicant's attorney would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

Dated: August 19, 2004

Respectfully submitted,

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